Workshop
on
Application for Listing Class II/III/IV Medical Devices

Medical Device Control Office
Department of Health

Workshop Agenda

- **Exercise 1 (Pre-workshop)**
- **Medical Device Administrative Control System (MDACS)**
- **Local Responsible Person（LRP）**
- **Classification of Medical Devices**
- **How to Prepare Application Documents**
- **Exercise 2 (Post-workshop)**

Exercise 1
(Pre-workshop)

Please complete and return Exercise 1

(Please do not read the handout)

Medical Device Administrative Control System (MDACS)

Medical Device Administrative Control System

- Voluntary system
- To be eventually superseded by a statutory system
- Aims:
  - To raise the public awareness of the use of safe medical devices
  - To enable traders to familiarize themselves with a system similar to the future mandatory requirements
  - To collect information and feedback from the industry to fine tune the long-term regulatory system

(Source: Page 20 of the Consultation Document dated July 2003 entitled "Regulation of Medical Devices")

Scope of MDACS

- Listing System
  - Medical Devices (**Classes II, III and IV**)
  - In vitro diagnostic (IVD) medical devices (Class D)
  - Local Manufacturers
  - Importers
  - Distributors
- Recognition of Conformity Assessment Bodies (CABs)
- Adverse Incident Reporting System
  - If a reportable incident concerning a listed device happens in Hong Kong, it must be reported by the LRP to MDCO. (Guidance Notes GN-03)


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Another workshop on Application for Listing Class II/III/IV Medical Devices (in English) will be held in August. Please watch out for details.
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>>More Events
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Safety alert on GE Healthcare nuclear medicine systems (8 July 2013)
>>More Press Release
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Summary of Safety Alerts (Updated on 23 Jul 2013)
Important Safety Alerts (Updated on 19 Jul 2013)
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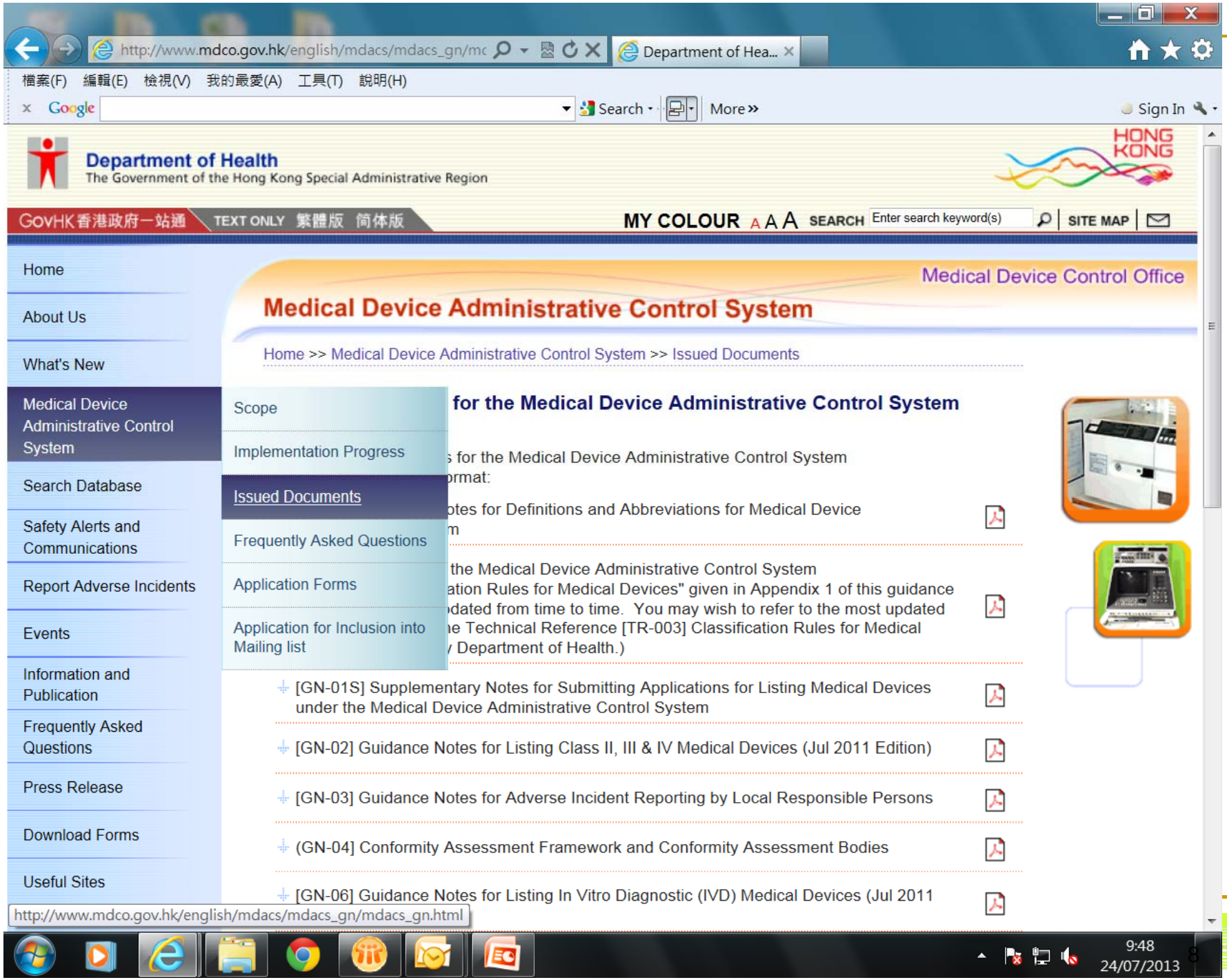
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ation Rules for Medical Devices" given in Appendix 1 of this guidance
dated from time to time. You may wish to refer to the most updated
e Technical Reference [TR-003] Classification Rules for Medical
Department of Health.)
[GN-01S] Supplementary Notes for Submitting Applications for Listing Medical Devices under the Medical Device Administrative Control System
[GN-02] Guidance Notes for Listing Class II, III & IV Medical Devices (Jul 2011 Edition)
[GN-03] Guidance Notes for Adverse Incident Reporting by Local Responsible Persons
(GN-04] Conformity Assessment Framework and Conformity Assessment Bodies
[GN-06] Guidance Notes for Listing In Vitro Diagnostic (IVD) Medical Devices (Jul 2011
http://www.mdco.gov.hk/english/mdacs/mdacs_gn/mdacs_gn.html
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Issued Documents

Guidance Notes	Document No.
Guidance Notes for Definitions and Abbreviations for MDACS	GN-00
Overview of the MDACS	GN-01
Guidance Notes for Listing Classes II, III & IV Medical Devices	GN-02
Guidance Notes for Adverse Incident Reporting by Local Responsible Persons	GN-03
Conformity Assessment Framework and Conformity Assessment Bodies	GN-04
Guidance Notes for Listing of Importers of Medical Devices	GN-07
Guidance Notes for Listing of Local Manufacturers	GN-08
Guidance Notes for Listing of Distributors	GN-09

Issued Documents

Technical References	Document No.
Principles of Conformity Assessment for Medical Devices	TR-001
Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)	TR-002
Classification Rules for Medical Devices	TR-003
Code of Practice	**Document No.**
Code of Practice for Local Responsible Persons	COP-01
Code of Practice for Conformity Assessment Bodies	COP-02
Code of Practice for Listed Local Manufacturers	COP-03
Code of Practice for Listed Importers of Medical Devices	COP-04

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Medical Device Control Office

Download Forms

Home >> Download Forms

Forms are available in both pdf and word formats:

- Application Form for Listing Class II/III/IV Medical Devices (MD-C2&3&4) (Jul 2011 Edition)
- Essential Principles Conformity Checklist (MD-CCL) (Jul 2011 Edition)
- Application for Recognition (or Change of Scope of Recognition) Under the Conformity Assessment Body Recognition Scheme of the MDACS (CAB-AA)
- Application for the Listing of Local Manufacturers (LM)
- Application for Inclusion on the List of Importers (MD-IP)
- Application for the Listing of In-Vitro Diagnostic Medical Devices (IVDMD) (Jul 2011 Edition)
- Medical Device Adverse Incident Report Form for use by Local Responsible Persons

Adobe Reader is required for viewing and printing the Portable Document Format (PDF) documents. To download Adobe Reader, please click here.

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d from the Universal Medical Device Nomenclature System (UMDNS). The
ms of these two systems are fully compatible and interchangeable. All new
g medical devices under the Medical Device Administrative Control System
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Local Responsible Person (LRP)

Who can be an LRP?

- A **legal person incorporated in Hong Kong** **or**
- a **legal or natural person with business registration** in Hong Kong; **and**
- who is itself the **manufacturer** **or** **supported by the manufacturer** (the manufacturer must designate the LRP in writing)

- ~~**Hong Kong permanent resident**~~

Sample Letter for Designating a LRP (GN-01 Appendix 5)

<Name of manufacturer>
<Address of manufacturer>

Date:

<Name of LRP>
<Address of LRP>

Dear Sirs,

Re: Designation of Local Responsible Person for <Brief description of devices>

In accordance with the requirements of the Medical Device Administrative Control System (MDACS) of the Hong Kong Special Administrative Region, we hereby designate you, <Name of LRP>, as the Local Responsible Person in respect of the following devices:

<Descriptions of devices including their makes, models, types, and other relevant identifiers>

This designation will require you to comply with, with immediate effect, all the requirements (including but not limited to all the pre-market and post-market requirements) that the MDACS imposes on you as the Local Responsible Person in respect of the above-mentioned devices. We undertake to provide you timely with all the items (documents, information, device and labelling samples etc.) and support that must necessarily originate from us, and which you will need in order to apply for the listing of the afore-mentioned devices and to fulfil your obligations under the MDACS. These items and support include but are not limited to:

(i) details of design related to the safety and performance of the device;
(ii) a copy of documents as required in the application form for the listing of devices;
(iii) any subsequent changes and modifications;
(iv) details of any recalls, alerts, and related preventive and corrective actions; and
(v) investigations and reports related to adverse incidents and post market surveillance.

Yours faithfully,

(signature)

(name and title of official signing this letter)

(official chop (if any) of the manufacturer)

Relationship between Manufacturer and LRP

- Two types of Manufacturer “Local” and ”Overseas”.
- Local Manufacturer can “designate” LRPs or becomes LRP by itself.

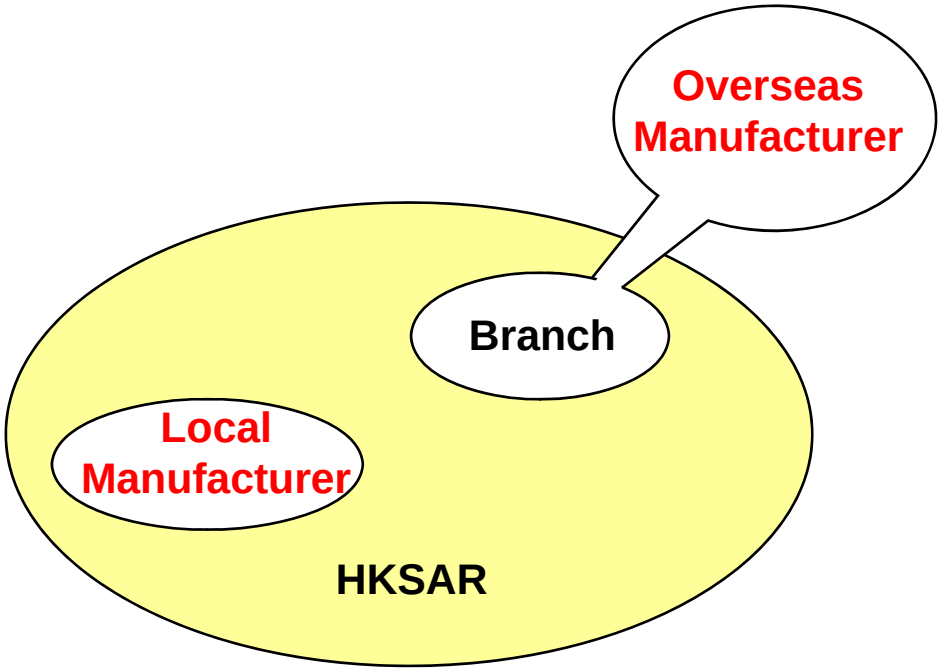


Figure 1

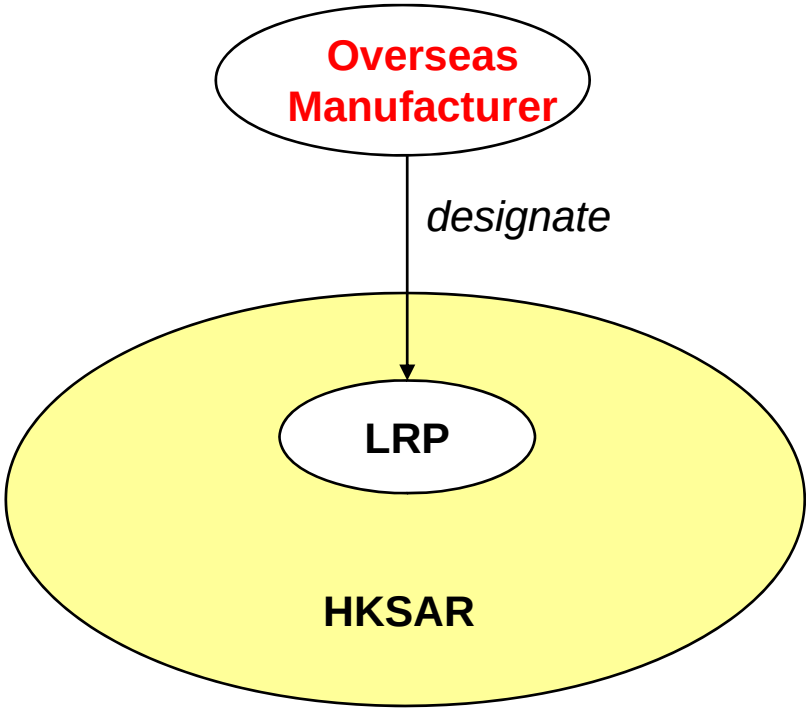
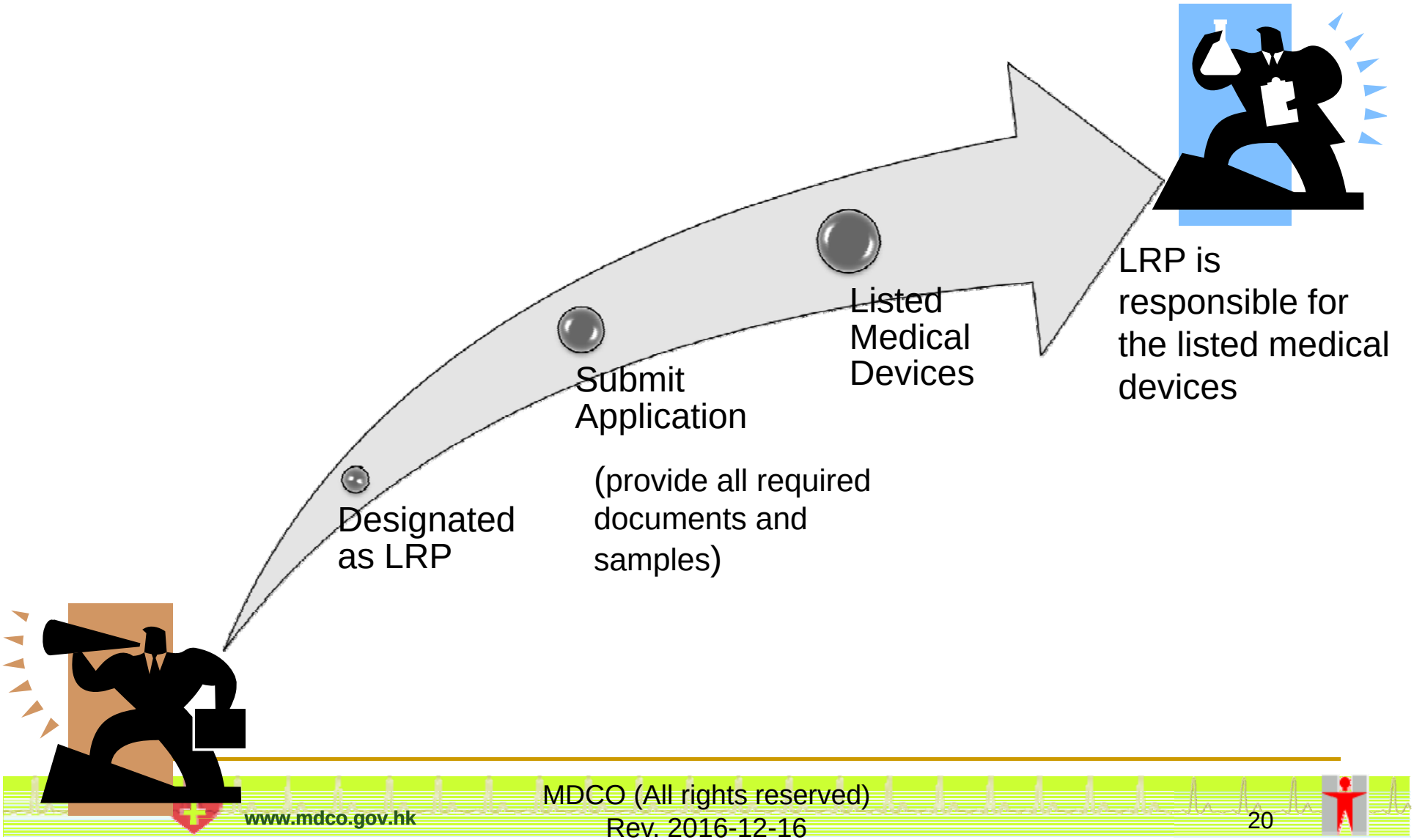


Figure 2

Relationship between Manufacturer and LRP

Type of Manufacturer	Itself	Designate
Local Manufacturer	✓	✓
Overseas Manufacturer （branch in Hong Kong）	✓ （H.K. Branch）	✓
Overseas Manufacturer (without branch in Hong Kong）	X	✓

Responsible Person for Listed Medical Devices



The LRP:

- is the applicant for Listing of medical devices
- should be based in HK for communicating with the MDCO, e.g., about Listing applications, etc.
- applies, **on his own initiative**, for renewal of Listing at least **3 months** before expiry of Listing

LRP's Responsibilities

Communications Hub

- Application for listing of medical devices
- Efficient communication channels
- Reporting changes
- Making records available for inspection
- Maintain distribution records

Safe and Efficacy

- Managing reportable adverse incidents in HK
- Product alerts, modifications and recalls
- Tracking of specific medical devices

Quality of Services

- Maintenance and services arrangements
- Compliant handling

Classification of Medical Devices

Definitions (Ref.: GN-00)

- **Medical Device:**

  any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, **intended by the manufacturer** to be used, alone or in combination, **for human beings** for one or more of the specific purpose(s) of :-

  - diagnosis, prevention, monitoring, treatment or alleviation of disease; or

  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury; or

Definitions (Ref.: GN-00)

- investigation, replacement, modification, or support of the anatomy or of a physiological process; or
- supporting or sustaining life; or
- **control of conception** ; or
- **disinfection of medical devices** ; or
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body;

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means.

Definitions (Ref.: GN-00)

- **Invasive device:**

  Device, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

- **Active medical device:**

  Device whose operation depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy.
  (Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, is not considered to be active medical devices.)

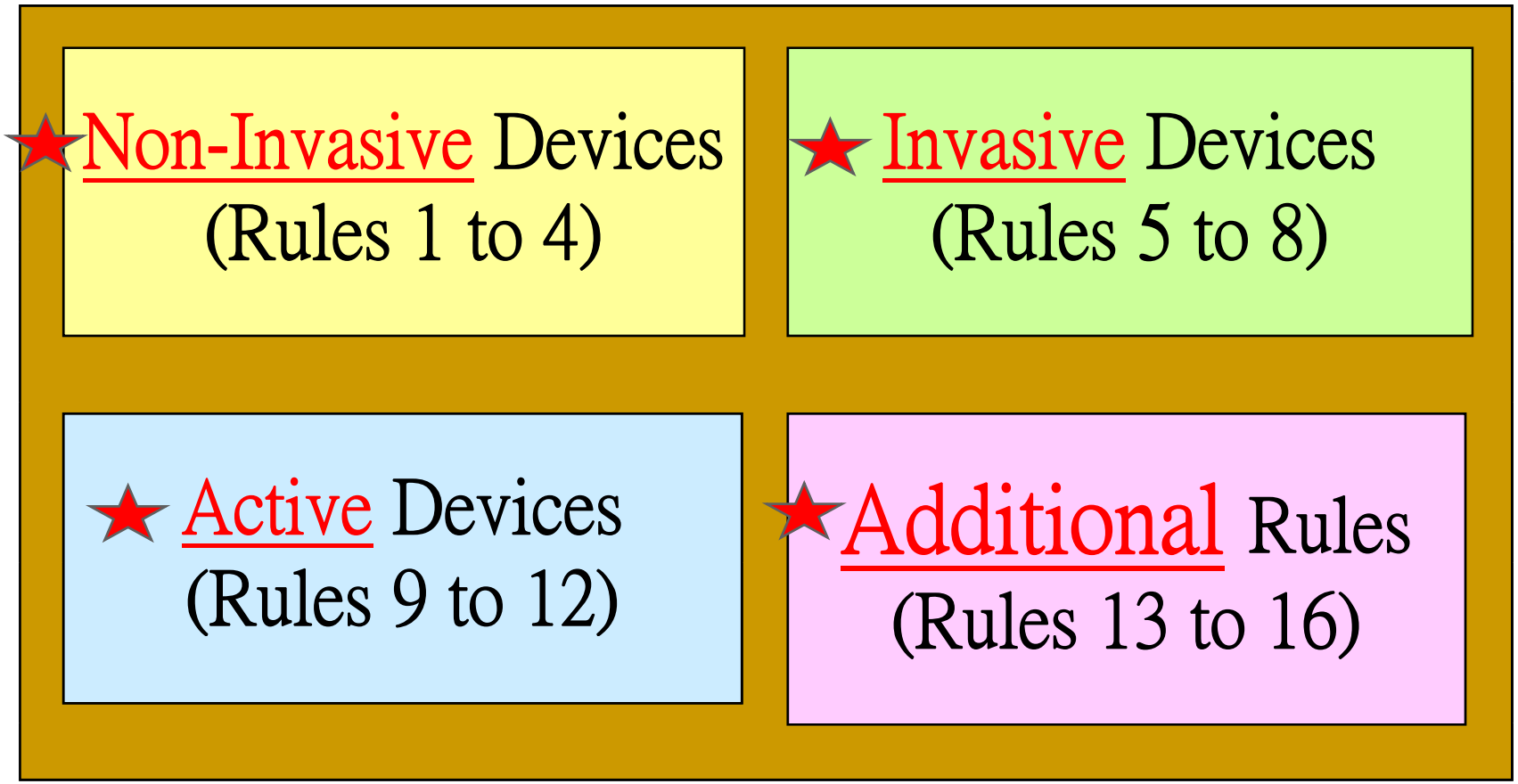
Definitions (Ref.: GN-00)

Transient use	normally intended for continuous use for **less than 60 minutes**
Short-term use	normally intended for continuous use for **between 60 minutes and 30 days**
★ **Long-term use**	normally intended for continuous use for **more than 30 days**

Classification of Medical Devices

- Class I (lowest risk) – Class IV (highest risk)
- Classification depends on:
  - Intended Use
  - Characteristics of the device, etc.
- All classification rules in TR-003 must be taken into consideration
- If more than one rule applies, the rule putting the device into the highest class prevails

Classification of Medical Devices



Classification of Medical Devices

Classification program:

http://www.mdco.gov.hk/english/faq/question.html

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Frequently Asked Questions

Web-based Medical Device Classification Program

Medical Device Classification Programme (Class I,II, III, IV medical devices)

Q1 Is this device incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices?

Yes No

Q2 Is this device manufactured from or incorporating animal or human cells / tissues / derivatives?

Yes No

Q3 Is this device intended specifically to be used for sterilising medical devices, or disinfecting as the end point of processing, but not intended to clean medical devices by means of physical action?

Yes No

Q4 Is this device used for contraception or the prevention of the transmission of sexually transmitted diseases?

Yes No

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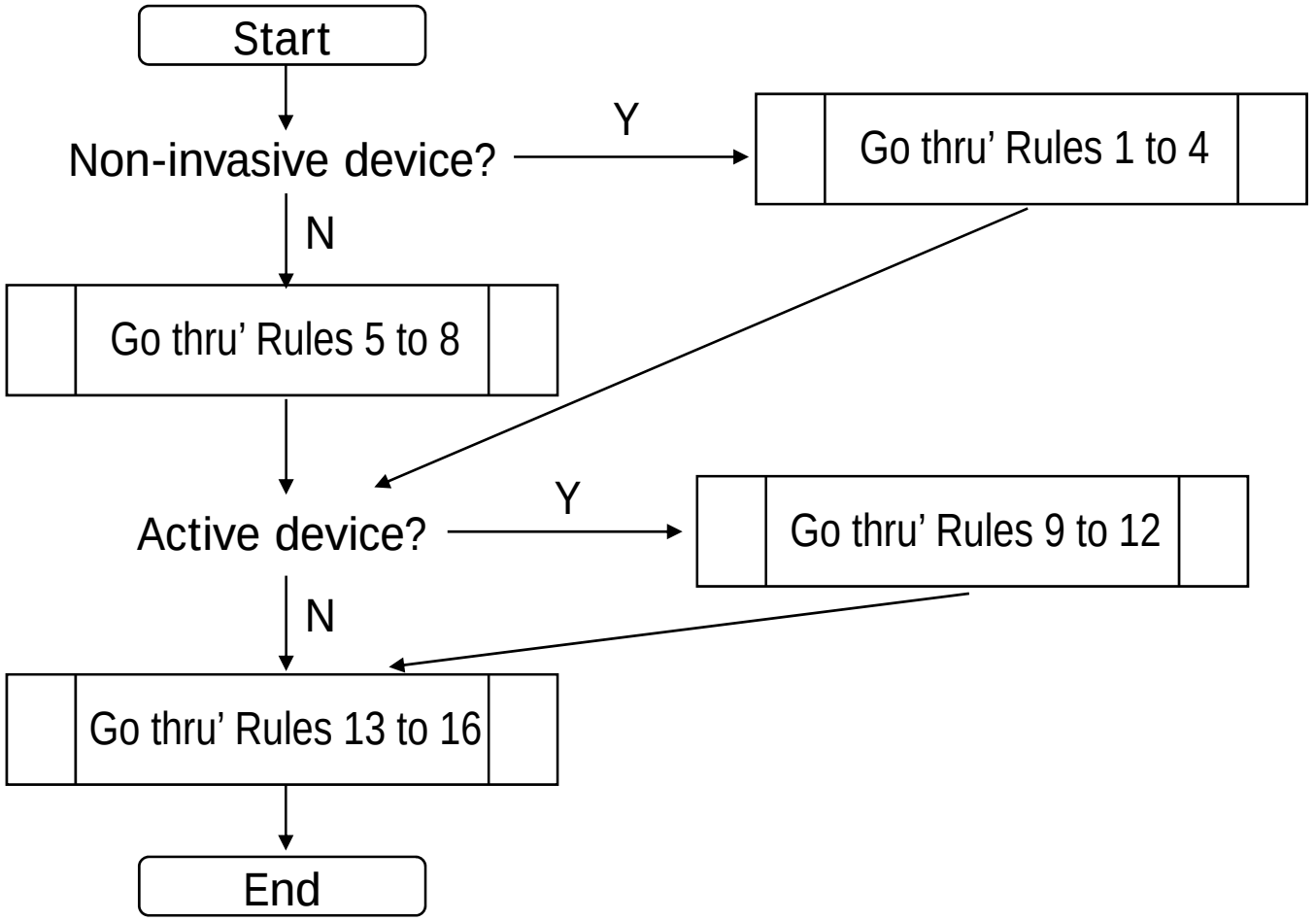
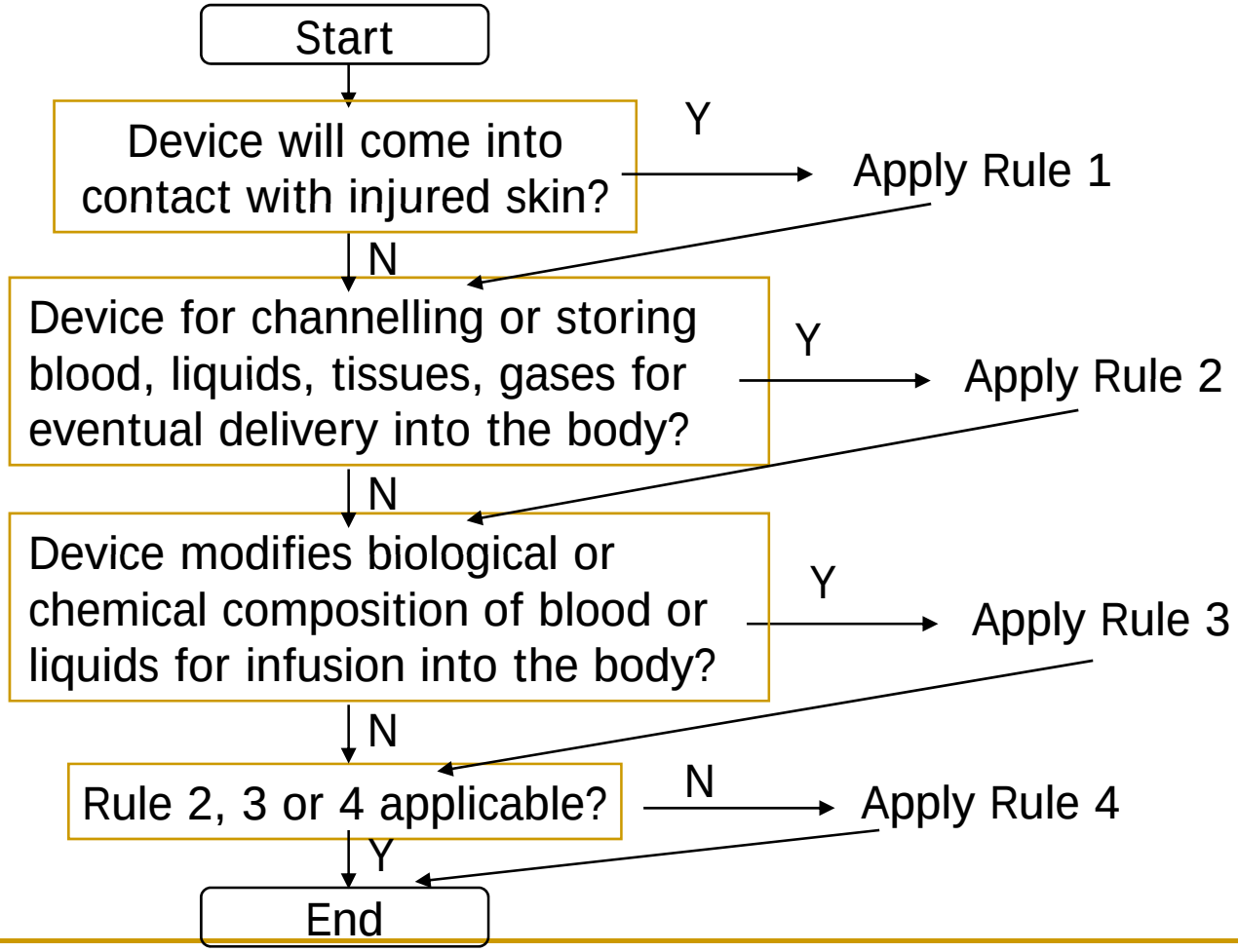
Disclaimer

The above classification programme are rough indications for references only. The actual classification of the medical devices is subject to the provision of the Medical Device Administrative Control Systerm (MDACS) which may be updated from time to time. The programme designer and the manager of this page take no responsibility for the

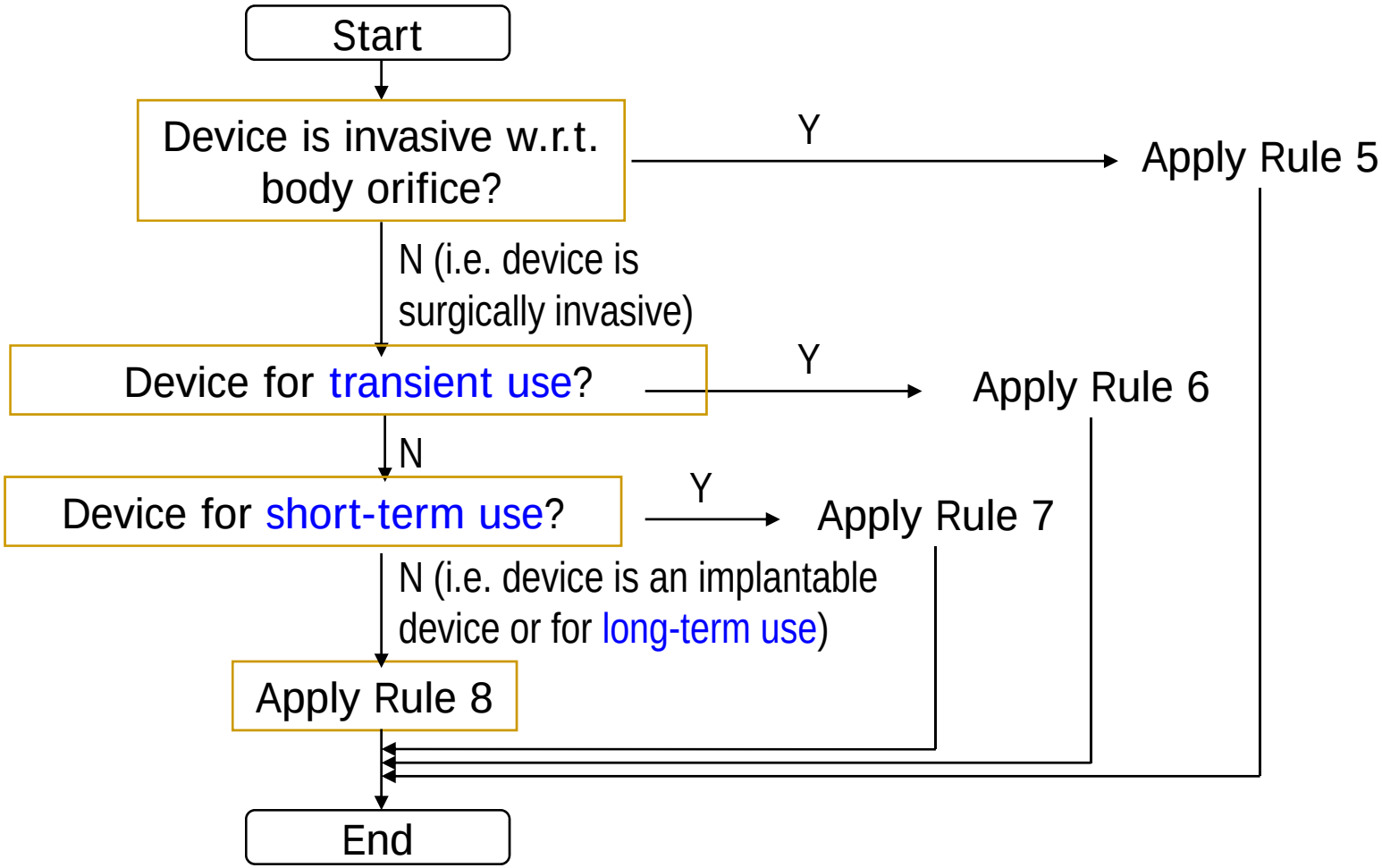
Classification of Medical Devices



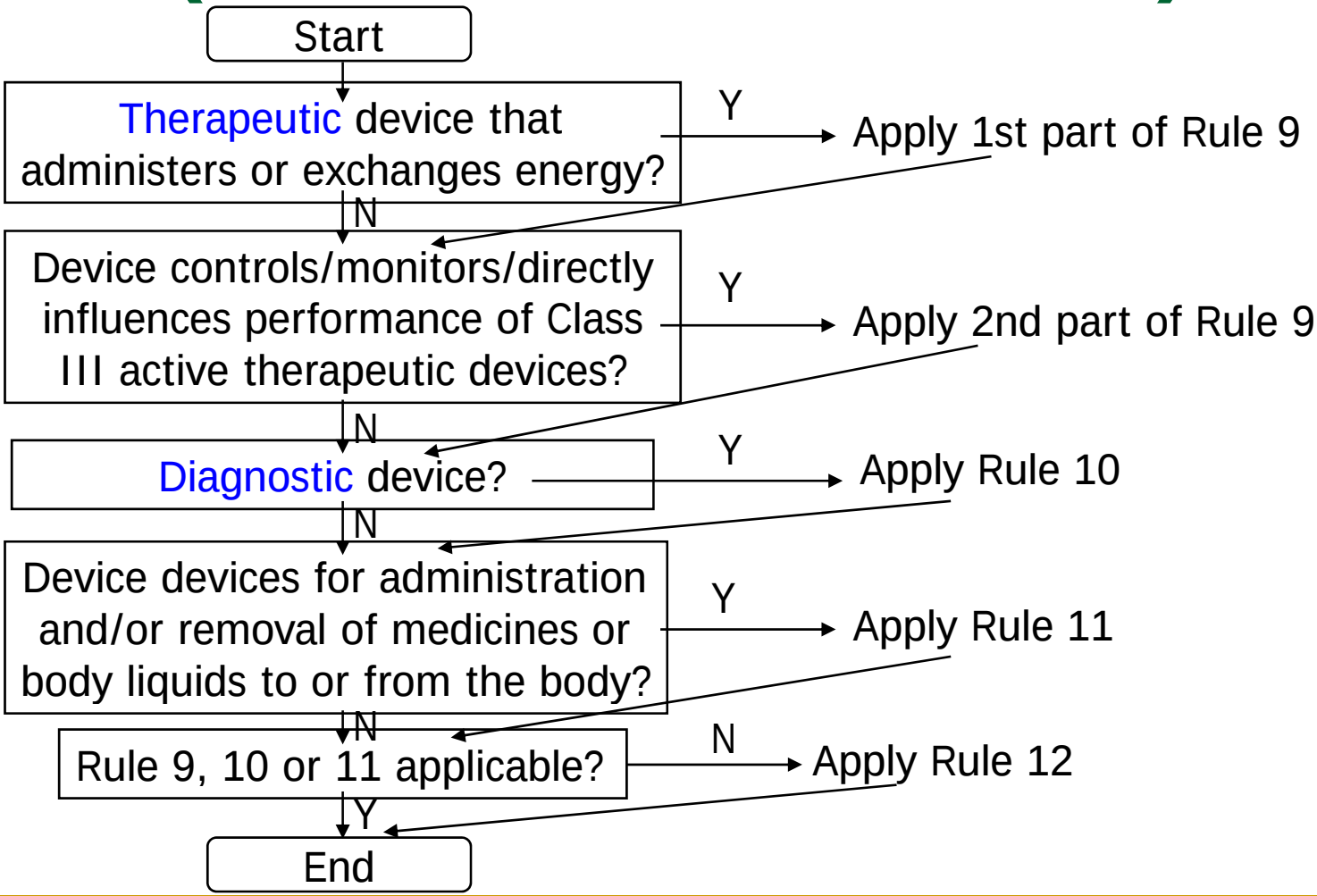
Go thru' Rules 1 to 4 (if the device is non-invasive)



Go thru' Rules 5 to 8 (if the device is invasive)



Go thru' Rules 9 to 12 (if the device is active)



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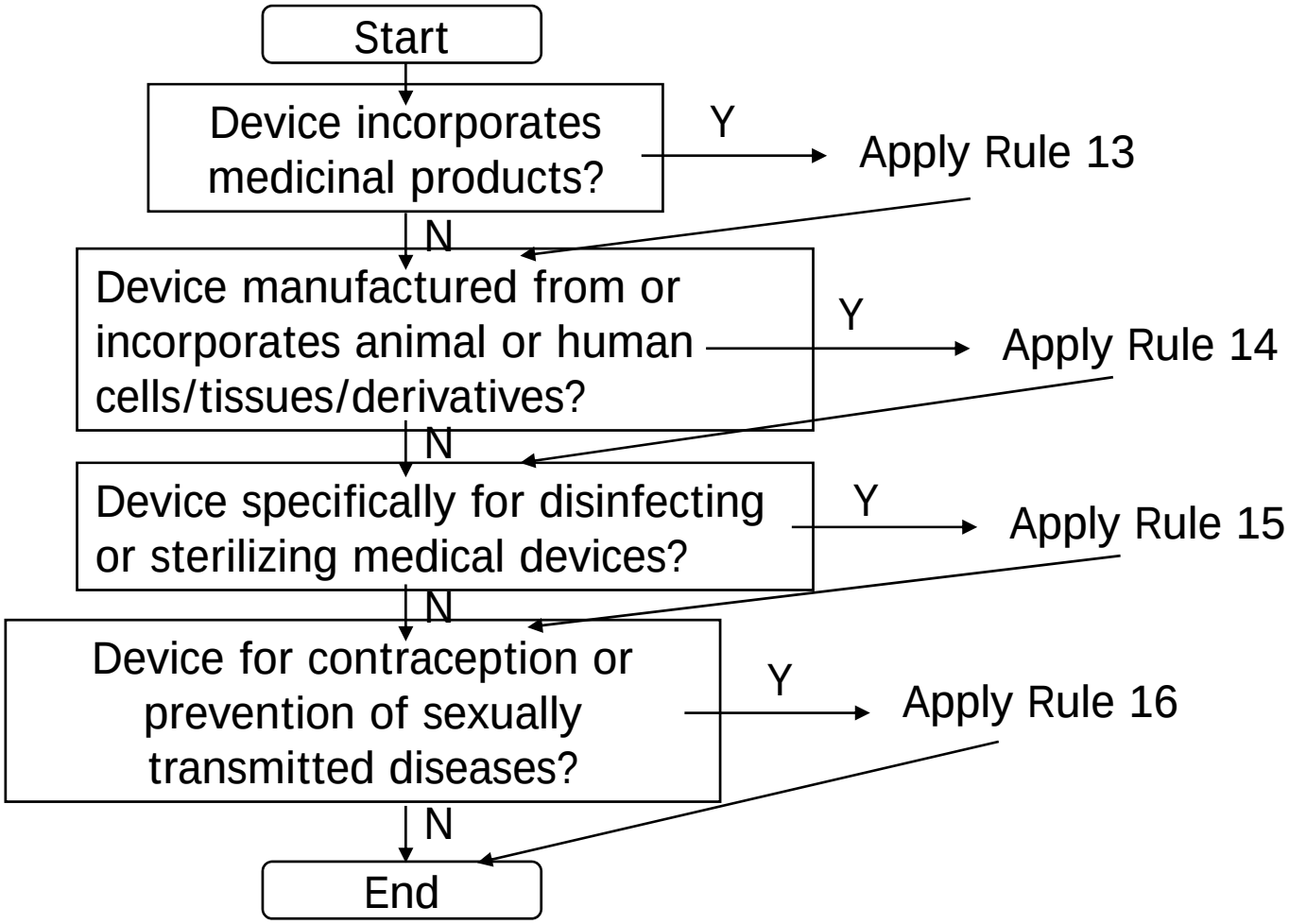
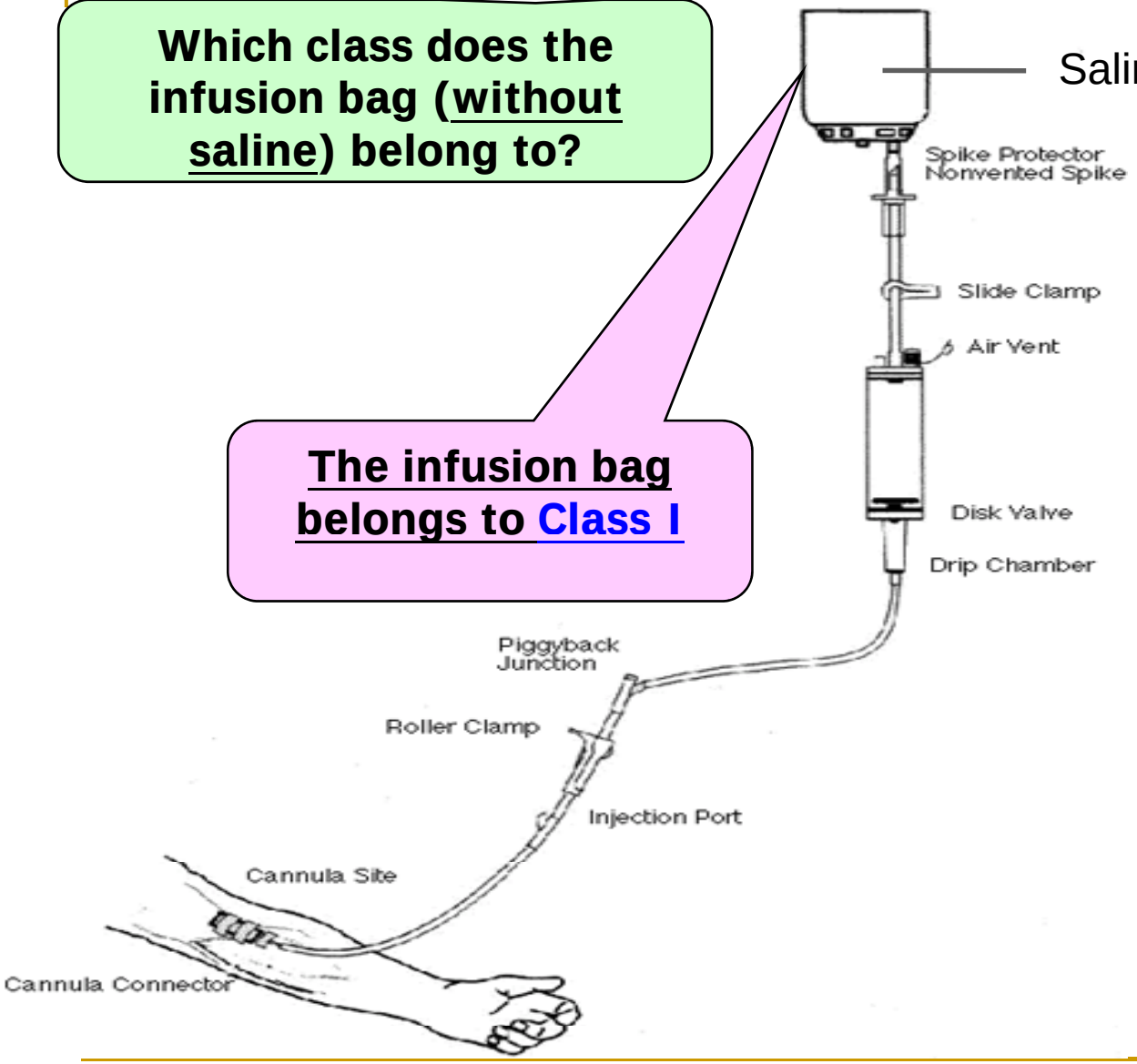
Go thru' Rules 13 to 16



Classification of Medical Devices – Question 1a

Which class does the infusion bag (without saline) belong to?

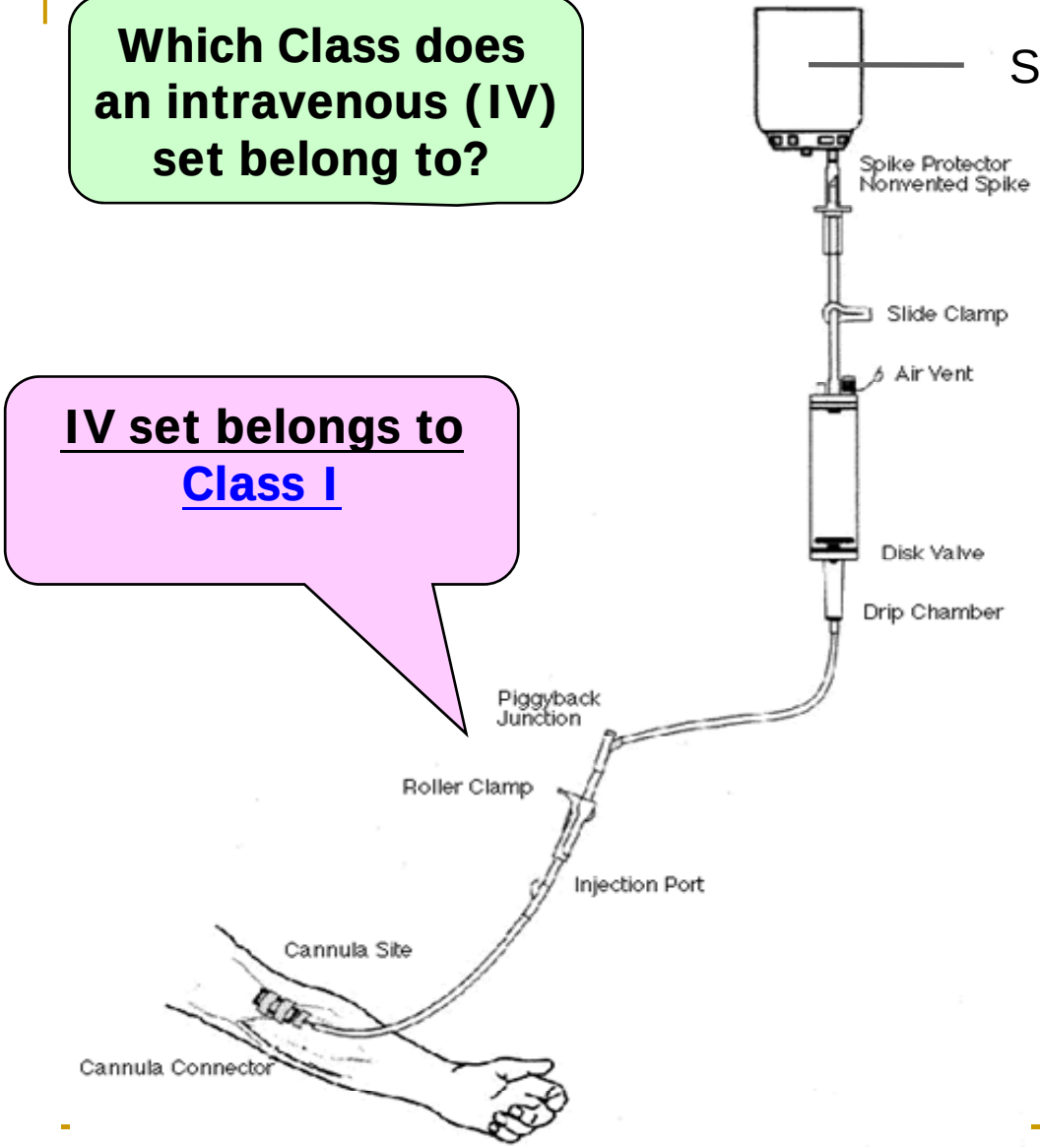


The infusion bag belongs to Class I

Which class does the device belong to?	
Classification rules	**Which rule applies?**
1 to 4 (for non-invasive devices)	**2**
5 to 8 (for invasive devices)	**N.A.**
9 to 12 (for active devices)	**N.A.**
13 to16 (additional rules)	**N.A.**

Classification of Medical Devices – Question 1b

Which Class does an intravenous (IV) set belong to?



IV set belongs to Class I

Which class does the device belong to?	
Classification rules	**Which rule applies?**
1 to 4 (for non-invasive devices)	**2**
5 to 8 (for invasive devices)	**N.A.**
9 to 12 (for active devices)	**N.A.**
13 to16 (additional rules)	**N.A.**

Classification of Medical Devices – Question 2

Electronic thermometer (oral)

Which class does the device belong to?	
Classification rules	**Which rule applies?**
1 to 4 (for non-invasive devices)	**N.A.**
5 to 8 (for invasive devices)	**5 (Class I)**
9 to 12 (for active devices)	**10 (i) (Class II)**
13 to16 (additional rules)	**N.A.**

Class II

Classification of Medical Devices – Question 3

Pulse Oximeter

Intended Use :
Intended for monitoring, recording and alarming of patient SpO2 in acute care settings in health care facilities.

Which class does the device belong to?	
Classification rules	**Which rule applies?**
1 to 4 (for non-invasive devices)	**4 (Class I)**
5 to 8 (for invasive devices)	**N.A.**
9 to 12 (for active devices)	**10 (i) (Class III)**
13 to16 (additional rules)	**N.A.**

Class III

Classification of Medical Devices – Question 4

Surgical Laser

All active therapeutical devices intended to administer or exchange energy are in Class II unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy, in which case they are **Class III**.

Which class does the device belong to?	
Classification rules	**Which rule applies?**
1 to 4 (for non-invasive devices)	**N.A.**
5 to 8 (for invasive devices)	**N.A.**
9 to 12 (for active devices)	**9 (i)**
13 to16 (additional rules)	**N.A.**

How to prepare an application

Sample completed application form (GN-02, Appendix 1)

Note	Part A: Particulars of Manufacturer				Encl.
A001	Manufacturer's name*	*in English*	*ABC Medical Ltd.*		
		in Chinese	*N.A.*		
	Address of Head Office*:	*in English*	*1324N. Derby Road, Arlington VA, USA*		
		in Chinese	*N.A.*		
	Post Code: *VA 12345-6789*			Country: *USA*	
	Contact person: *John Smith*			Telephone: *800.332.2354*	
	Fax: *703.276.0314*			E-mail: *jsmith@abcmed.com*	
	Website*: *http://www.abcmedical.com*				

Form MD-C2&3&4 (Jul 2011 Edition)

A002	☐ Registered place of business in Hong Kong: ☐ Copy of business registration certificate (with business registration number _____) is enclosed Contact person: / Telephone: Fax: / E-mail:	(A1) ☐
A003	Established Quality Management System ☒ Full quality management system covering device design, production, and post-production processes ☐ Partial quality management system covering processes: _____ _____ Standards with which the system complies: ☒ ISO13485:2003 or later edition (ISO13485:_____) ☒ System certified by *CAB Systems Ltd* (certification body), and a copy of the certificate is enclosed	(A2) ☒
A004	Has the manufacturer designated any Local Responsible Person (LRP)? *(N.B. If the manufacturer has no registered place of business in Hong Kong, it must designate a legal person incorporated in Hong Kong or a natural or legal person with a registered place of business in Hong Kong as the LRP.)* ☒ Yes ☐ No, manufacturer itself acts as the LRP	

Note	Part B: Particulars of Local Responsible Person (LRP)			Encl.
B001	LRP's name*	*in English*	*CARDIO SUPPLIES LTD.*	(B1) ☒
		in Chinese	*心臟儀器供應有限公司*	
	Address in Hong Kong *(Please give the registered place of business, if any)**	*in English*	*32/F., METROPOLITAN CENTRE, 123 MERRY STREET, CAUSEWAY BAY, HONG KONG*	
		in Chinese	*香港銅鑼灣喜樂街123號都市中心32樓*	
	Contact person: *CHAN TAI-MAN*		Telephone: *2800 0000*	
	Position: *General Manager*		E-mail: *tchan@cardio.com.hk*	
	Contact telephone for public enquiries * : *2000 0000*		Fax: *2900 0000*	
	Mobile telephone for urgent use (24 hours): *9000 0000*			
	☒ Copy of business registration certificate (with business registration number: *BR123467*) is enclosed			
B002	Date designated as LRP by the manufacturer: *30 June 2010* ☒ Manufacturer's designation letter is enclosed			(B2) ☒
B003	Established Quality Management System ☐ ISO9001:2000 ☒ ISO9001:2008 or later edition ☐ ISO13485:2003 or later edition ☐ None ☒ System certified by *ABC Agency* (certification body), and a copy of the certificate is enclosed			(B3) ☒

B004	Documented Procedures Established and Maintained ☒ The applicant does not have any medical device listed under the Medical Device Administrative Control System ☒ The procedures indicated in items (i) to (iv) below are enclosed; AND ☒ The procedures indicated in items (v) to (vi) have been established and will be submitted upon request. (i) Keeping of distribution records (ii) Management of product recalls and field safety notices (iii) Handling of reportable adverse incidents in Hong Kong (iv) Tracking of specific medical devices (if applicable) (v) Complaints handling (vi) Maintenance and service arrangements (if applicable) ☐ The applicant already has one or more medical device listed under the Medical Device Administrative Control System (**LRP number:** _____) ☐ There is no change to the procedures indicated in items (i) to (iv). *(Please go to B005)*; OR ☐ The procedures indicated in items (i) to (iv) have been updated and enclosed.	(B4) ☒
B005	☒ The LRP is also an importer of the device named in Part C Listing No. of Importer: IMP0123456 (if applicable)	
B006	☐ The device named in Part C is currently a listed device (under another LRP), with Listing No._____.	

Note	Part C: Particulars of the Device			Encl.
C001	Make*	*in English*	*ABC Medical*	
		in Chinese	*N.A.*	
	Brand Name*	*in English*	*VGOOD*	
		in Chinese	*N.A.*	
	Model*	*in English*	*PMS-123*	
		in Chinese	*N.A.*	
C002	☐ A single medical device ☐ A medical device family ☐ A medical device series ☒ A medical device system For a medical device family, medical device series or a medical device system, please provide the additional information required in a format similar to MDS-01. ☒ Additional information similar to MDS-01 attached			(C1) ☒
C003	Description of the device: *(Please enter the appropriate AMDNS term. If none of the terms in AMDNS appear appropriate, enter a short description of the device.)* *MONITORING SYSTEMS, PHYSIOLOGIC*			
	AMDNS Code: *12636*			
	Other Codes *(Please enter if known):*			

C004	Other common descriptions of the device: *PATIENT MONITORING SYSTEM*			
C005	Intended use of the device*	*in English*	*A physiologic monitoring system intended for monitoring, recording and alarming of multiple physiological parameters depending on which modules are equipped. It is indicated for use in acute care settings in health care facilities by health care professionals whenever there is a need for monitoring physiological parameters of adult, paediatric or neonatal patients.*	
		in Chinese	*病人監護儀用以監察及記錄病人的多項生理參數（視乎裝設哪些組件而定），並在適當時發出警報。醫護專業人員在醫護設施的急症護理環境中，如需監護患病成年人、兒童或初生嬰兒的生理參數，便可使用該監護儀。*	
C006	Accessories and parts covered by the Marketing Approvals and Essential Principles Conformity Checklist under Note D001 of Part D. *Please provide its identifier(s) (e.g. part number) and description using a format similar to MDS-02.* ☒ Additional information similar to MDS-02 attached			(C1) ☒

C007

1. The device

Yes	No	
☐	☒	incorporates, as an integral part, a medicinal product which could act on the human body with action ancillary to that of the device
☐	☒	is manufactured from or incorporating human cells/tissues/derivatives
☐	☒	is manufactured from or incorporating animal cells/tissues/derivatives

2. The device

- ☐ is a **non-active device** *(please go to section 3)*
- ☒ is an **active device**
  - ☐ intended to control or monitor the performance of active therapeutic devices in Class III, or intended directly to influence the performance of such devices
  - ☒ intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient
  - ☒ intended for diagnosing in clinical situations where the patient is in immediate danger
  - ☐ intended to administer or exchange energy to or from human body in a potentially hazardous way including ionizing radiation
  - ☐ none of the above

C007

3. The device

☒ is a **non-invasive device**

- ☐ comes into contact with injured skin (e.g. wound dressings) *(please complete section 4)*
- ☒ connected to an active medical device in Class II or a higher class
- ☐ intended for channelling blood, or storing or channelling other body liquids, or for storing organs, parts of organs or body tissues
- ☐ intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body
- ☐ none of the above

☐ is an **invasive device**

- ☐ invasive with respect to body orifices (other than those surgically invasive)
- ☐ intended to be connected to an active medical device in Class II or a higher class
- ☐ intended for use in oral cavity, ear canal or nasal cavity
- ☐ intended to supply energy in the form of ionizing radiation
- ☐ intended to have biological effect or be wholly or mainly absorbed
- ☐ intended to administer medicinal products by means of a delivery system and is potentially hazardous
- ☐ intended for use in direct contact with the central nervous system or to diagnose, monitor or correct a defect of the heart of central circulatory system through direct contact
- ☐ intended to undergo chemical change in the body
- ☐ none of the above

and is intended for *(please check the applicable item only)*

- ☐ transient use (< 60 mins)
- ☐ short-term use (between 60 mins and 30 days)
- ☐ long-term use (> 30 days)

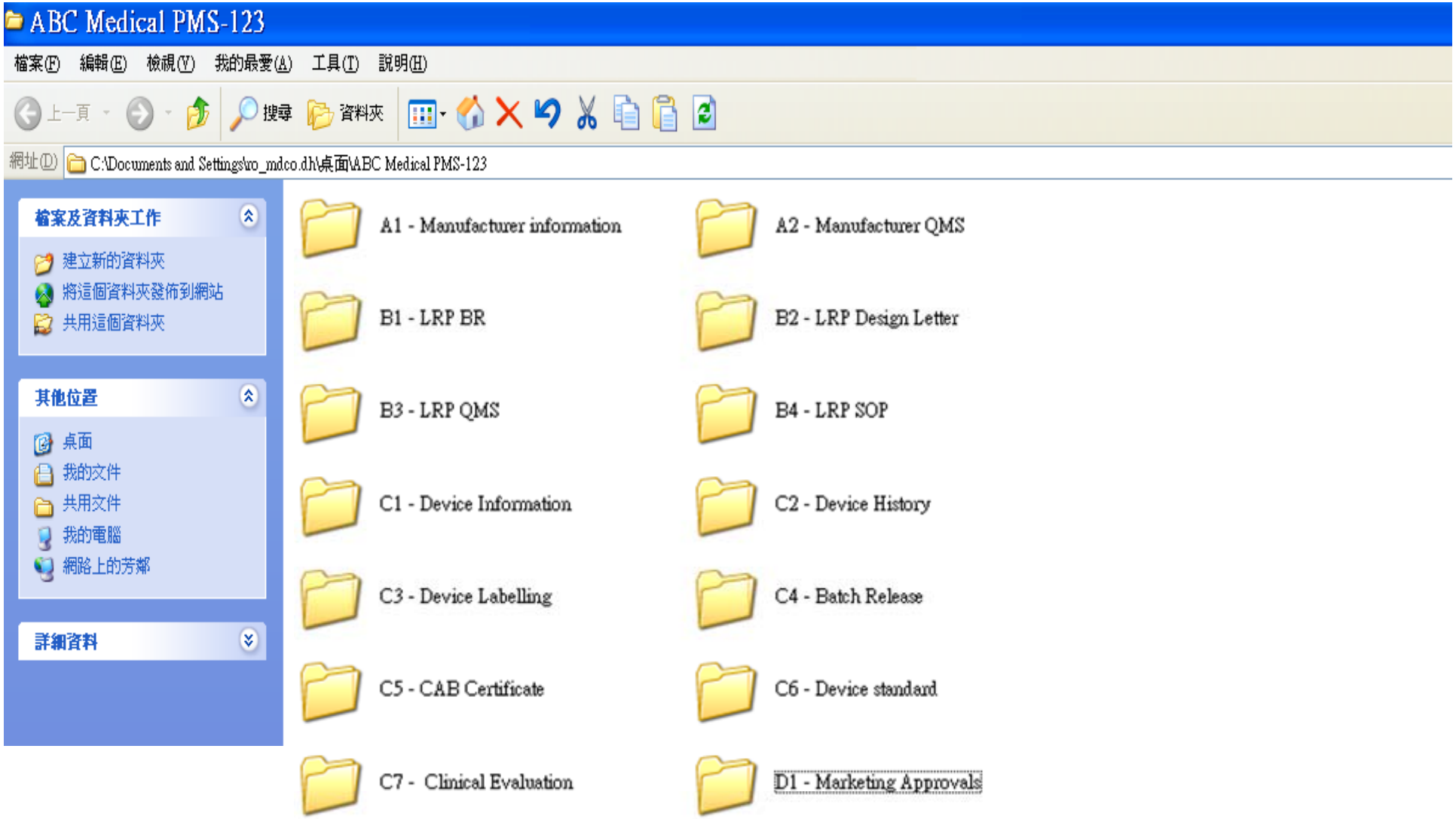
	4. The device is a wound dressing ☐ intended to be used as a mechanical barrier, for compression of wounds or for absorption of exudates (e.g. simple wound dressing; cotton wool) ☐ intended to manage the microenvironment of wounds (e.g. non-medicated impregnated gauze dressings) ☐ intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent (e.g. dressings for chronic ulcerated wounds). ☐ impregnated with medicinal products (e.g. medicated gauze dressings)	
C008	Class of the medical device: ☐ Class II ☒ Class III ☐ Class IV	
	Reasons for classifying the device as Class II/III/IV device: *It is an active device intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient (Rule 10(i))*	
C009	Manufacturing Site(s) *(Use separate sheet if required)*: *(1) 1324N, Derby Road, Arlington, VA 12345-6789, USA* *(2) 1000 Butler Road, Plymouth Place, PA 12486-1248, USA*	(C1) ☒

C010	History of previous recalls, reportable adverse incidents, banning in other countries or post-market surveillance studies ☐ No ☒ Yes (Please check the appropriate boxes and provide details): ☐ Recalls completed or in progress ☒ Reportable adverse incidents bearing implications to the device ☐ The device banned previously in other countries ☐ Proactive post-market surveillance studies	(C2) ☒
C011	Usage ☐ The device is for single use ☐ The device is supplied as sterile product ☐ Disposal of used device or any part thereof (including any used accessories or consumables) requires special precautions. ☐ The device is intended to be used/operated by healthcare professionals only ☐ The device is intended to be used/operated by laypersons ☐ It is intended for self-use	
C012	Repair and Servicing ☒ The device requires regular servicing/testing/checking/calibration ☒ Repairs and servicing provided by the LRP or appointed party in Hong Kong ☐ All repairs and servicing performed in Hong Kong ☒ Part of the repairs and servicing performed in Hong Kong ☒ Technical support provided by the manufacturer	

C013	Labelling Requirements Instructions for use are available (Note: Devices intended for self-use by consumers must be accompanied by instructions for use written in both English and Chinese): ☒ in English ☐ in Chinese ☒ A set of device labelling copies is enclosed ☒ Sample of Special Listing Information is enclosed Please indicate where in the labelling the following information is given: (1) Indications for use of the device: *Pages 4 – 8 of the operator's manual* (2) Contraindications against use of the device: *Pages 9 – 11 of the operator's manual* (3) Cleaning, disinfection and/or sterilization procedures: *Pages 45 of the operator's manual* (4) User precautions: *Pages 24 – 28 of the operator's manual* (5) Disposal precautions: *N. A.*	(C3) ☒
C014	Licencing Requirements The device is subject to provisions under the following ordinances and a copy of the required licence(s) is/are enclosed: Yes No ☐ ☒ Radiation Ordinance (Cap. 303) ☐ ☒ Pharmacy and Poisons Ordinance (Cap. 138) ☐ ☒ Antibiotics Ordinance (Cap. 137) ☐ ☒ Dangerous Drugs Ordinance (Cap. 134)	(C4) ☐

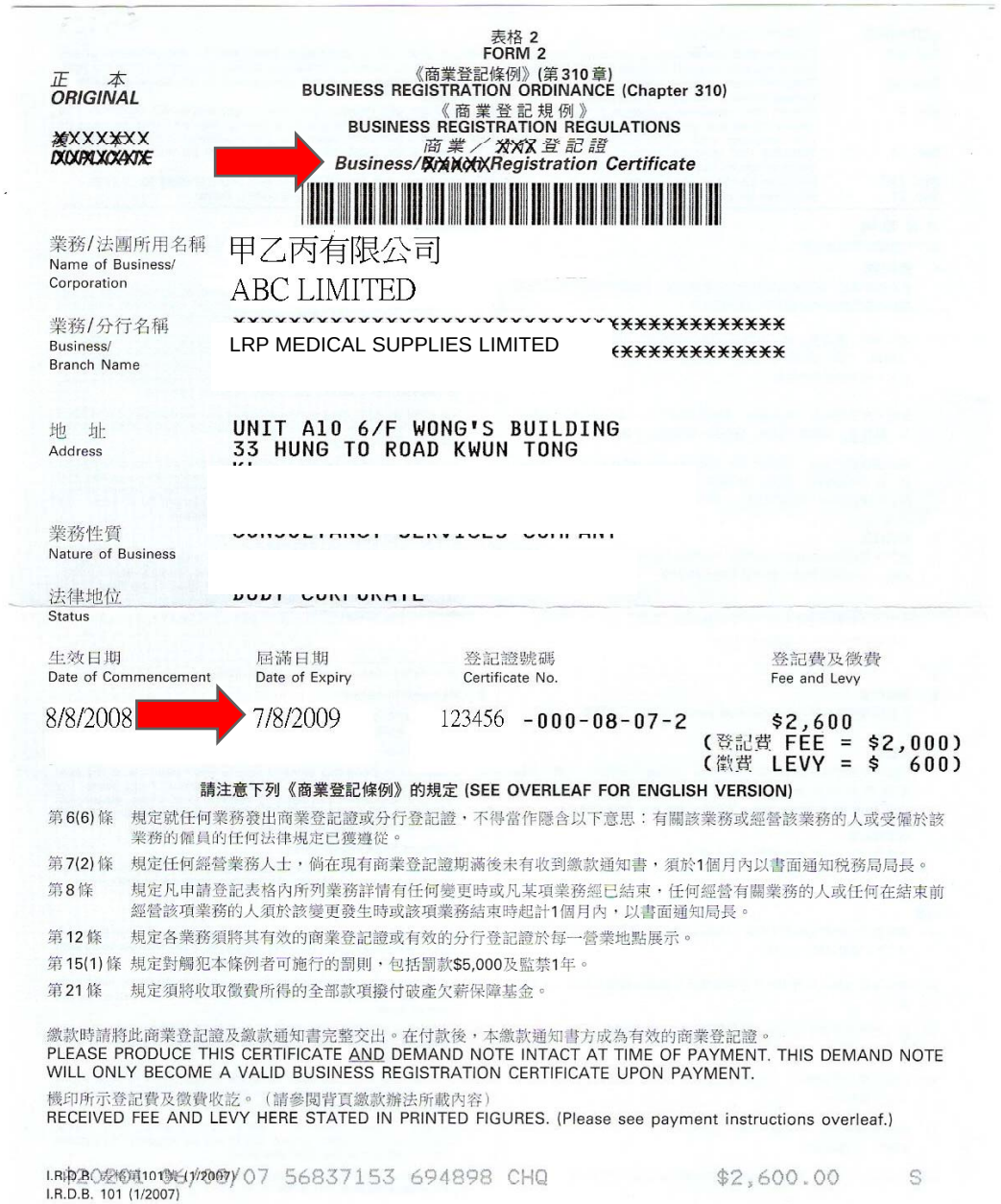
C015	Conformity Assessment ☐ MDACS Conformity Assessment Certificate issued by one of the Conformity Assessment Bodies recognized by MDCO MDACS Conformity Assessment Body number: _____	(C5) ☐
C016	Safety and Risk Analysis International or national safety standards with which the device complies: *(1) IEC 60601-1:1988+ A1:1991+A2:1995; (2) IEC 60601-1-2:2004; (3) IEC 60601-1-8:2003; (4) IEC 60601-2-49:2001* ☒ Risk analysis conducted: report or summary is enclosed ☒ Type test performed: report or test certificate is enclosed	(C6) ☒
C017	Clinical Evaluation ☒ Clinical investigation report of the device is enclosed ☐ Demonstration of equivalence to another device (equivalent device) where safety and efficacy of which are well established: ☐ Clinical investigation report of the equivalent device and a report of demonstration of equivalence are enclosed ☐ Report demonstrating full equivalence to a well established product is enclosed	(C7) ☒

Note	Part D: Marketing Approvals and Essential Principles	Encl.
D001	Marketing Approvals in Foreign Countries ☒ Approval obtained for the medical device to be placed on the market of the following countries: ☐ Australia (The Therapeutic Goods Administration) ☐ Canada (Health Canada) ☒ Member countries of European Union that have implemented the European Council Directives 90/385/EEC and 93/42/EEC and a copy of the EC Declaration of Conformity is enclosed ☐ Japan (Ministry of Health, Labour and Welfare) ☒ United States of America (U.S. Food and Drug Administration) ☐ Earliest approval obtained on or before 31 December 2004 ☒ Earliest approval obtained on or after 1 January 2005 ☒ Essential Principles Conformity Checklist MD-CCL is enclosed; OR ☐ Essential Requirements Checklist in accordance with the EU Medical Device Directives and Essential Principles Declaration of Conformity are enclosed	(D1) ☒



LRP

Business Registration Certificate (B1)



表格 2
FORM 2
《商業登記條例》(第310章)
BUSINESS REGISTRATION ORDINANCE (Chapter 310)
《商業登記規例》
BUSINESS REGISTRATION REGULATIONS

正 本
ORIGINAL

商業／[illegible]登記證
Business/[illegible]Registration Certificate

業務/法團所用名稱
Name of Business/
Corporation

甲乙丙有限公司
ABC LIMITED

業務/分行名稱
Business/
Branch Name

LRP MEDICAL SUPPLIES LIMITED

地 址
Address

UNIT A10 6/F WONG'S BUILDING
33 HUNG TO ROAD KWUN TONG

業務性質
Nature of Business

法律地位
Status

生效日期 Date of Commencement	屆滿日期 Date of Expiry	登記證號碼 Certificate No.	登記費及徵費 Fee and Levy
8/8/2008	7/8/2009	123456 -000-08-07-2	$2,600 (登記費 FEE = $2,000) (徵費 LEVY = $ 600)

請注意下列《商業登記條例》的規定 (SEE OVERLEAF FOR ENGLISH VERSION)

第6(6)條 規定就任何業務發出商業登記證或分行登記證，不得當作隱含以下意思：有關該業務或經營該業務的人或受僱於該業務的僱員的任何法律規定已獲遵從。

第7(2)條 規定任何經營業務人士，倘在現有商業登記證期滿後未有收到繳款通知書，須於1個月內以書面通知稅務局局長。

第8條 規定凡申請登記表格內所列業務詳情有任何變更時或凡某項業務經已結束，任何經營有關業務的人或任何在結束前經營該項業務的人須於該變更發生時或該項業務結束時起計1個月內，以書面通知局長。

第12條 規定各業務須將其有效的商業登記證或有效的分行登記證於每一營業地點展示。

第15(1)條 規定對觸犯本條例者可施行的罰則，包括罰款$5,000及監禁1年。

第21條 規定須將收取徵費所得的全部款項撥付破產欠薪保障基金。

繳款時請將此商業登記證及繳款通知書完整交出。在付款後，本繳款通知書方成為有效的商業登記證。
PLEASE PRODUCE THIS CERTIFICATE AND DEMAND NOTE INTACT AT TIME OF PAYMENT. THIS DEMAND NOTE WILL ONLY BECOME A VALID BUSINESS REGISTRATION CERTIFICATE UPON PAYMENT.

機印所示登記費及徵費收訖。（請參閱背頁繳款辦法所載內容）
RECEIVED FEE AND LEVY HERE STATED IN PRINTED FIGURES. (Please see payment instructions overleaf.)

[illegible] 07 56837153 694898 CHQ $2,600.00 S

I.R.D.B. 101 (1/2007)

Local Responsible Person (LRP)

Manufacturer's designation letter (B2)

(See GN-01, Appendix 5)

Appendix 5

Sample Letter for Designating a Local Responsible Person

<Name of manufacturer>
<Address of manufacturer>

Date:

<Name of LRP>
<Address of LRP>

Dear Sirs,

Re: Designation of Local Responsible Person for <Brief description of devices>

In accordance with the requirements of the Medical Device Administrative Control System (MDACS) of the Hong Kong Special Administrative Region, we hereby designate you, <Name of LRP>, as the Local Responsible Person in respect of the following devices:

<Descriptions of devices including their makes, models, types, and other relevant identifiers>

This designation will require you to comply with, with immediate effect, all the requirements (including but not limited to all the pre-market and post-market requirements) that the MDACS imposes on you as the Local Responsible Person in respect of the above-mentioned devices. We undertake to provide you timely with all the items (documents, information, device and labelling samples etc.) and support that must necessarily originate from us, and which you will need in order to apply for the listing of the afore-mentioned devices and to fulfil your obligations under the MDACS. These items and support include but are not limited to:

(i) details of design related to the safety and performance of the device;
(ii) a copy of documents as required in the application form for the listing of devices;
(iii) any subsequent changes and modifications;
(iv) details of any recalls, alerts, and related preventive and corrective actions; and
(v) investigations and reports related to adverse incidents and post market surveillance.

Yours faithfully,

(signature)

(name and title of official signing this letter)

(official chop (if any) of the manufacturer)

LRP designation letter (B2):

- Issued by the manufacturer

★ - **Contains:**

✓Manufacturer’s name

✓Manufacturer’s address

✓LRP’s name

✓LRP’s address

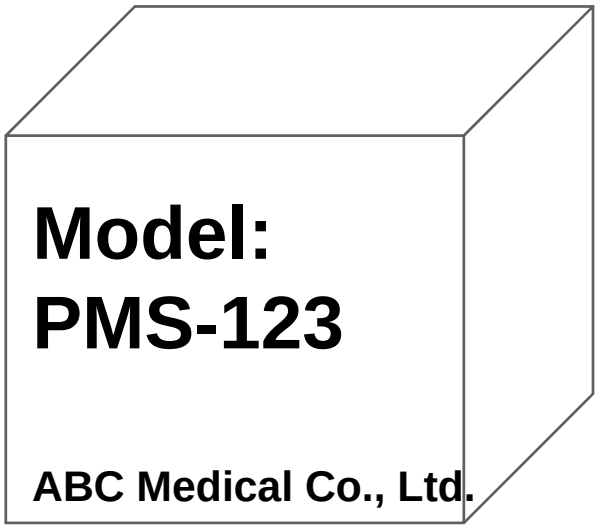
✖ ~~LRP’s tel./fax~~

LRP's documented procedures (B4)

- Procedures to be submitted in the 1st application for Listing of medical devices:
  - ✓Keeping of distribution records
  - ✓Management of product recalls and field safety notices
  - ✓Handling of reportable adverse incidents in HK

- ~~Customer survey~~

Medical Device



Family/Series/ System

Accessories

Manufacturing site(s)

(C1)

Recalls/Adverse Incidents / Banning

(C2)

Labelling samples:
LRP information (Name/address/Tel.), Listing No. (HKMD No.), IFUs, product/package labels

(C3)

If applicable: Wholesale Poisons Licence, Antibiotics Permit, Irradiating Apparatus Licence, etc.

(C4)

If applicable: HK MDACS Conformity Assessment Certificate

(C5)

Type Test Certificate/Report

Risk Analysis Report

(C6)

Clinical evaluation report

(C7)

(C3)

- Devices intended for self-use by consumers must be accompanied by instructions for use written in both English and Chinese
- Special Listing Information contains:
  - ✓Listing no. (HKMD No.)
  - ✓LRP's name
  - ✓LRP's address
  - ✓LRP's tel./fax
  - ~~LRP's email address~~

Medical Device (D1) EU Approval

EC (CE) Certificates	
EC Design-Examination Certificate	MDD, Annex II, section 4 AIMD, Annex 2, section 4
EC Type Examination Certificate	MDD, Annex III AIMD, Annex 3
Full Quality Assurance System Approval Certificate	MDD, Annex II, section 3 AIMD, Annex 2, section 3
EC Verification Certificate	MDD, Annex IV AIMD, Annex 4
Production Quality Assurance System Approval Certificate	MDD, Annex V AIMD, Annex 5
Product Quality Assurance System Approval Certificate	MDD, Annex VI

MDD – Medical Device Directive (93/42/EEC); AIMD – Active Implantable Medical Device Directive (90/385/EEC)

儀器 (D1)

Medical Device Control Office
Department of Health

Medical Device Administrative Control System
Essential Principles Conformity Checklist

Make: _____

Brand Name and Model: _____

Clause	Essential Principle	Applicable	Method of Conformity	Identity of Specific Documents
General Requirements				
1.	Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	Y	ISO13485: 2003--Medical devices -- Quality management systems -- Requirements for regulatory purposes ISO14971:2007--Medical devices -- Application of risk management to medical devices	Document No. DMF1234
2.	The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risks associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed: • identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse, • eliminate risks as far as reasonably practicable through inherently safe design and manufacture, • reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms, • inform users of any residual risks.	Y		
3.	Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device.	Y		
4.	The characteristics and performances referred to in Clauses 1, 2 and 3 should			

儀器 (D1)

- Essential Principles Conformity Checklist (form MD-CCL) is not required if the earliest foreign marketing approval is obtained **in or before 2004**

儀器 (D1)

[redacted] **ESSENTIAL REQUIREMENTS CHECKLIST**

File No.	[redacted]
Rev. No.	0
Rev. Date	2009.10.29
Page	1 of 10

Essential Requirements	A-N/A	Standards	Manufactures and Compliance	Locations
I.GENERAL REQUIREMENTS				
1. The devices must be designed and manufactured in such a way that, when user under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of user or, where applicable other persons provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of health and safety.	A	*EN ISO 14971* *EN ISO 14155-1* *EN ISO 14534* *EN ISO 14729* *EN ISO 14730* *EN ISO 14971* *EN ISO 13485*	*- Risk management report(NVTC-210-RM)* *- Product standard(NEO-SOL-004)* *- Quality manual and procedures* *- Test reports(MSK191~ MSK-195)*	*QM Dept.*
2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. in selecting the most appreciate solutions, the manufacturer must apply the following principles in the following order -eliminate or reduce risks as far as possible(inherently safe design and construction) -where appropriate take adequate protection measures including alarms if necessary, in relation to risks that must not be eliminated. -inform users of the residual risks due to any shortcomings of the protection measures adopted.	A	*EN ISO 14971* *EN ISO 14155-1* *EN ISO 13485* *EN ISO 14534* *EN ISO 14729* *EN ISO 14730*	*- Risk management report(NVTC-210-RM)* *- Clinical Evaluation Report (NVTC-210-CER)* *- Product standard(NEO-SOL-004)* *- Quality manual and procedures* *- Labeling and Packaging Instruction (NEO-SOL-WS Series)* *- Test reports (MSK191~ MSK-195)*	*QM Dept.*
3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1(a) as specified by the manufacturer.	A	*EN ISO 14971* *EN ISO 13485* *EN ISO 14534* *EN ISO 14729* *EN ISO 14730*	*- Risk management report(NVTC-210-RM)* *- Product standard(NEO-SOL-004)* *- Labeling and Packaging Instruction (NEO-SOL-WS SERIES)* *- Test reports (MSK191~ MSK-195)*	*QM Dept.*
4. The characteristics and performance referred to in Selection 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which must be occur during normal conditions of use.	A	*EN ISO 14971* *EN ISO 14155-1* *EN ISO 13485* *EN ISO 14534* *EN ISO 14729* *EN ISO 14730*	*- Risk management report(NVTC-210-RM)* *- Clinical Evaluation Test(NVTC-210-CER)* *- Product standard(NEO-SOL-004)* *- Quality manual and procedures* *- Test reports (MSK191~ MSK-195)*	*QM Dept.*

[redacted]

儀器 (D1)

Sample of
Essential Principles
Declaration of
Conformity
(see GN-02, Appendix 3)

Appendix 3

<Name of Manufacturer/Local Responsible Person>
<Address of Manufacturer/Local Responsible Person>
<Date>

Medical Device Control Office,
Department of Health,
Room 3101, 31/F., Hopewell Centre,
183 Queen's Road East,
Wan Chai,
Hong Kong

Dear Sirs

Product: <Make> and <Model(s)>
<Product Description>
Manufactured by <Manufacturer>
<Address of Manufacturer>

We declare that the captioned product fully complies with all the relevant clauses stipulated under the Essential Principles of Safety and Performance of Medical Devices as required under the Medical Device Administrative Control System. We undertake to provide the necessary evidence to demonstrate the compliance within two weeks upon request.

Yours faithfully

<Signature>
<Name and Title>
<Company Name>

Exercise 2
(Post-workshop)

Please complete and return
Exercise 2 and evaluation form

Many thanks!

Thank you!

（The content of this presentation serves as reference only. Please refer to the Medical Device Control Office for details of MDACS）